

## **HAND SANITIZER- ethyl alcohol gel**

### **SJ Creations, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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## **Drug Facts**

### **Active Ingredient(s)**

Ethyl Alcohol 65% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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### **Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

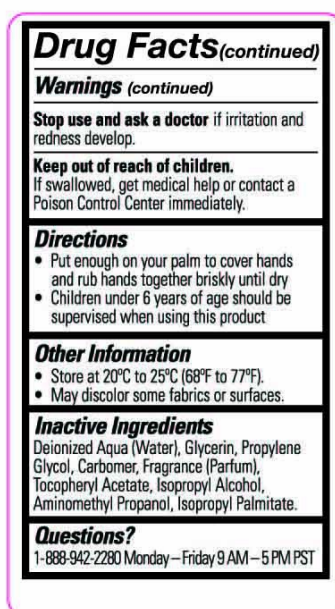
## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

Water, Glycerin, Propylene Glycol, Carbomer, Fragrance, Tocopheryl Acetate, Isopropyl Alcohol, Aminomethyl Propanol, Isopropyl Palmitate.

## Package Label - Principal Display Panel



59ml: NDC 43269-935-02

## HAND SANITIZER

ethyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43269-935
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

<b>WATER</b> (UNII: 059QF0KO0R)				
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)				
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)				
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)				
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)				
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:43269-935-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/07/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part333A	03/30/2020	

**Labeler -** SJ Creations, Inc. (146379495)